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Rutan & Tucker, LLP. Hani Z. Sayed 611 ANTON BLVD SUITE 1400 COSTA MESA, CA 92626			EXAMINER LIU, SUE XU	
			ART UNIT 1639	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,986

Applicant(s)

KURESHY ET AL.

Examiner

Sue Liu

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Please note the change of examiner for this application. (Please see the Conclusion paragraph for information on any future correspondence.)

Claim Status

Claim 7 has been canceled as filed on 3/15/07.

Claims 1-6 and 8-20 are currently pending.

Claims 11-20 have been withdrawn.

Claims 1-6 and 8-10 are being examined in this application.

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-10) in the reply filed on 3/15/07, is as previously acknowledged.
2. Claims 11-20 are withdrawn from further consideration as drawn to non-elected invention.

Priority

3. This application is filed under 35 U.S.C 371 of PCT/US03/17382 (filed on 05/28/2003), which claims priority to US provisional applications 60/383,896 (filed on 5/28/2002) and PCT/US02/17006 (filed on 05/28/2002).

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Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Applications No. 60/383,896 and PCT/US02/17006, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claimed "second energy source", "second energy detect", "...without passing across a wall of a tip", and "without the portion of the first energy passing across the wall" do not appear to have support in the said priority documents.

Thus, the said subject matter of the instant application does not obtain the benefit of the earlier priority date. The effective filing date of the said subject matter is 5/28/2003.

Claim Rejections Withdrawn

4. In light of applicants' amendments to the claims and supporting arguments, the following claim rejections as set forth in the previous office action are withdrawn:

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A.) Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(Note: the instant claim numbers are in bold font.)

Kureshy and Sakka

6. Claims 1-3, 5, 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kureshy et al (US 5,141,871; 8/25/1992), in view of Sakka et al (US 5,271,902; 12/21/1993). The previous rejection is maintained for the reasons of record as set forth in the previous Office

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action as well as the discussion below. The rejection over claim 7 is moot due to applicant's cancellation of the said claims.

The instant claims recite an analytic device with an automatic pipette, comprising:

a robotic arm that is structurally coupled to (1) **a pipette tip** receiving element wherein the robotic arm *is configured to translate the pipette tip receiving element along at least two of an x-coordinate, a y-coordinate, and a z-coordinate*, and (2) **a manipulator** that is configured to *push a biochip from one location in the analytic device to another location*, wherein the manipulator *is configured to be movable in a linear and in a rotational motion*;

wherein the pipette tip receiving element is further structurally coupled to **a sensor** that *detects presence of a disposable polymer pipette tip that is removably coupled to the pipette tip receiving element*;

a first energy source and **a first energy detector** operably coupled to the pipette tip receiving element such that the first energy source *provides a first energy to a volume that is enclosed by the pipette tip without passing across a wall of the tip*, and such that *the first energy detector receives at least a portion of the first energy from the volume without the portion of the first energy passing across the wall of the tip*;

a second energy source and **a second energy detector** structurally coupled to the pipette tip receiving element such that the second energy source *provides a second energy to a surface of a biochip when the pipette tip approaches the surface of the biochip and such that the second energy detector receives at least part of the second energy from the surface*; and

a processor electronically coupled to the first and second energy detectors, wherein the processor *is configured to calculate an controls accurate aspiration volume of a predetermined volume using a signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.*

The instant claims are drawn to a product of an analytic device comprising various components. The instant claim 1 is construed to comprise the following structural elements: a robotic arm, a pipette tip receiving element, a manipulator, a sensor, a first energy source, a first energy detector, a second energy source, a second energy detector, and a processor. The above recitation in *italic* of the instant claim (claim 1) are construed as intended uses and/or functions of the claimed device.

Kureshy et al, throughout the patent, teach an analytical instrument comprising various components. (e.g. Abstract; Figures). The reference teaches in the Abstract and in column 4, lines 5-9, an analytical device with an automatic pipette, (e.g. shown in Figure 1 as elements 40/42). Furthermore, the pipette receiving element (e.g. element 44 of Fig 1) is coupled to a mechanism (e.g. element 64, Figure 2) that translates the pipette tip receiving element in at least two dimensions (see, for example, column 4, lines 8-9; lines 17, 21 wherein the transport mechanism (e.g. element 64) provides for relative movement in two dimensions), which read on the robotic arm coupled to a pipette tip receiving element of **clm 1**. The mechanism (e.g. element 64 of Figure 2) is shown to be capable of performing translatory movement, and thus read on the

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recited functions of “to translate the pipette tip...” of **clm 1**. The reference also teaches a “carousel” (e.g. element 24 of Figure 2) for supporting and moving assay cartridges (such as a “biochip”), which the carousel reads on the “movable” “manipulator” and the recited function of “linear and rotational motions” of **clm 1**.

The reference also teaches the pipette receiving elements are coupled to a detection system comprising a sensor for detecting the presence/absence of disposable tips (e.g. element 108 of Figure 2; col. 5, lines 13+; column 1, lines 45-46; column 5, lines 55-56; column 10, lines 3-9, see also, Figure 5, and Figure 6 such that the presence of the tip interrupts the light beam (first optical energy source which is signaled to the microprocessor), which read on the pipette coupled sensor and the sensor’s function of **clm 1**.

The reference also teaches the detection system comprise an energy sources (i.e. a source of light; e.g. element 110 of Figure 2; col.5, ll 13+; claim 6) and a detector (e.g. element 112 of Figure 2; col.5, ll 13+; claim 6), which read on the first/second energy source and energy detector of **clm 1**.

The reference also teaches in column 4, lines 56-59; and column 5, lines 15-17, the optical detection system signals when the tip of the pipette (attached to the pipette receiving element) has advanced in the downward direction to a predetermined distance from a selected compartment of the cartridge (e.g., a biochip), which read on the intended uses and/or functions of the claimed device of **clm 1**.

The reference also teaches microprocess for processing the signals from the detector (e.g. element 62 of Figure 2; col.5, lines 45+), which read on electronic processor and the intended use of **clm 1**.

Kureshy et al, teach light beam is applied to a tip containing a volume to be dispensed (e.g. column 7, lines 31-33) and the light beam is provided through a light source (infrared radiation) (e.g. element 110 of Figure 2; col.5, ll 19+), which the infrared radiation light beam reads on the laser and the light guide of **clm 2**.

Kureshy et al, also teach the intended use as recited in **clm 3**. For examples, the reference teaches the signal generated by reflection of light as the pipette tip crosses the light beam to the energy detector that begins the aspiration and dispensing step. (e.g. Figure 2, element 28 and Figure 7).

Kureshy et al., teach (see column 5, lines 21-24) an optoelectronic sensor, which reads on **clm 5**.

Kureshy et al, teach (see element 146, Fig 4; col.8, lines 20+) a data transfer interface, a microprocessor and/or a computer as parts of the device, which at least the “computer” reads on **clm 8** as well as the intended use recitation of **clm 9**. The “computer” unit of the reference inherently has the capabilities of export data and remotely transfer data. The intended use language of **clm 9** does not result in a structural difference between the claimed apparatus and the prior art of Kureshy, and does not patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Kureshy et al, teach a sample station with movable table for stationing sample fluids and pipette tips (e.g. Fig 2, elements 66 and 68; col.4, ll. 1+), which read on **clm 10** limitations.

Kureshy et al do not explicitly teach an additional sensor/detector as recited in **clm 1**. The reference also does not explicitly teach the intended use of attaching the pipette receiving

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element with a pipette tip that can hold equal or less than 200 microliter in volume, as recited in **clm 6**.

However, Sakka et al, throughout the patent, teach a similar sample handling apparatus with various sensor/detector and pipette receiving elements (e.g. Abstract). Sakka et al., (see column 5, lines 8-22; col. 8, ll 10+) teach a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and wherein first energy detector receives at least a portion of the first optical energy from the volume; Sakka et al., (see column 7, lines 47-55) teach a processor electronically coupled to the first and second energy detectors, wherein the processor controls accurate aspiration of a predetermined volume using a Signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.

Sakka et al., also teach (see column 6, lines 38-41), the pipette tip has a volume of equal or less than 200 microliter (invention is effective in taking out quantitatively a sample in small amounts, particularly from 1 to 150 microliter).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include an additional sensor/detector for various purpose such as for aspirating and dispensing an accurate volume of fluid as well as providing a pipette for attaching pipette tips with desired volume size.

A person of ordinary skill in the art would have been motivated to combine the first energy source and the first energy detector coupled to the pipette tip receiving element creating a liquid level detecting device with Kureshy et al., because the liquid level detecting device of

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Sakka, et al., provides a device that is capable of detection at higher sensitivity in comparison with the more traditional type of devices. Also, the liquid detection system of Sakka provides a way to simultaneously and rapidly conduct liquid level detection and liquid sample suction of a micro-quantity of liquid without cross-contamination of the sample.

A person of ordinary skill in the art would have been motivated to use a pipette tip that can hold a desired volume such as 200 microliter, because the one of ordinary skilled in the art would choose the desired tip size based on experimental design. For example, Sakka et al, teach that for particular assays such as immune measurements, volume of 200 ul is desired. In addition, the small volumes such as 200ul of the pipette tips offer the advantages such as effective in taking out quantitative small sample volumes for various experimental applications.

Finally, a person of ordinary skill in the art would have had a reasonable expectation of success because utilizing the system described by Sakka et al., because it has well known, robust elements for reliably detecting and quantifying a fluid volume and dispensing the fluid appropriately.

Kureshy, Sakka and Laugharn

7. Claims 1-6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kureshy et al (US 5,141,871; 8/25/1992), and Sakka et al (US 5,271,902; 12/21/1993) in view of Laugharn, et al (US 6,948,843; 9/27/2005; filed 3/20/2001 or earlier priority date; cited previously). The previous rejection is maintained for the reasons of record as set forth in the previous Office action as well as the discussion below. The rejection over claim 7 is moot due to applicant's cancellation of the said claims.

Kureshy et al, throughout the patent, teach an analytical instrument comprising various components. (e.g. Abstract; Figures), as discussed above.

Sakka et al, throughout the patent, teach a similar sample handling apparatus with various sensor/detector and pipette receiving elements (e.g. Abstract), as discussed supra.

The combination of the Kureshy and Sakka references does not explicitly teach using an “ultrasound transducer” as the second energy source, as recited in **clm 4**.

However, Laugharn et al., throughout the patent teach using acoustic energy to control liquid motion (e.g. Abstract). The reference teaches in column 2, line 42, an energy source (acoustic energy source) e.g. such as an ultrasound transducer.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the energy source and detection systems and a way of aspirating and dispensing an accurate volume of fluid and a way of mixing the fluid sample taught by Laugharn et al.

A person of ordinary skill in the art would have been motivated to combine and modify the analytical instrument of Kureshy et al., to include an ultrasound transducer taught by Laugharn et al., because the ultrasound transducer provides a way of mixing the sample. Mixing a sample with small volumes like the ones taught by the claimed invention helps to insure accurate distribution of the sample and this provides a more uniform uptake of the sample. By modifying the invention of Kureshy in this manner, this meets the requirement of Kureshy et al., to ensure that an accurate fluid volume is dispensed into an assay cartridge (e.g., a biochip) of a predetermined size range. Also mixing the samples before aspirating and dispensing provides another mechanism to ensure accuracy of the volume in fluid uptake because it minimizes air

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bubbles present. This also provides for an even distribution of the fluid sample for uptake, which at very low volumes is crucial for accuracy. Minimizing the presence of air bubbles in a sample also helps to increase the reflection of energy transmission. Interfaces between air and water for example, result in efficient reflection of an incident ultrasound field.

Furthermore, one final example of an advantage of this system is no direct contact of the fluid to be mixed and the sonic energy source is required. This combination allows for a more accurate determination of the fluid volume to be dispensed in a very small area of the cartridge thus providing a basis for improving an area where complications have been previously encountered.

Finally, a person of ordinary skill in the art would have had a reasonable expectation of success because utilizing the system described by Laugharn, Jr., et al., because it has well known, robust elements for reliably non-contact mixing a fluid sample.

Discussion and Answer to Argument

8. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that not all elements of the instant claims are taught by the cited references. Specifically, applicants argue the following recitations are not taught by the references:

a.) a robotic arm...

b.) a pipette...

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c.) a manipulator...

(Reply, pp.5+)

Applicants are respectively directed to the above discussion under the body of the rejection over the cited references for detailed analysis of how the references' teachings read on the instant claimed invention.

Applicants further stated the followings:

"On the contrary, as the fluid recipient in Kureshy is on a rotating platform that is enclosed in a temperature controlled housing, there is clearly no motivation to modify Kureshy such as to arrive at a device as presently claimed as such modification would require an static and open platform. [sic]" (Reply, p.6, para 1).

Applicants made the above statement without further elaborating on why the modification "would require an static and open platform" [sic], and on how a "static and open platform" would be structurally different from the instantly claimed device.

Applicants also argue because the "detection system 108 is structurally coupled to the temperature controlled housing and not to the pipette tip receiving element", the reference (Kureshy) does not teach the instant claimed element. (Reply, p.16, para 2-3 and p.7, para 3).

The instant claim 1 recites the following:

"a first energy source and a first energy detector operably coupled to the pipette tip receiving element";

“a second energy source and a second energy detector structurally coupled to the pipette tip receiving element”.

The “108 element” of the Kureshy reference, as discussed supra, can be used to measure either the fluid volume in the tip or the vertical position of the pipette tip (relative to the biochip surface). The terms “operably coupled” and “structurally coupled” are not specifically defined in the instant specification to limit the “detectors” to be attached directly to the “pipette tip receiving element” itself. The term “coupled” is also not specifically defined in the instant specification to mean a direct linkage of one element to another.

The case laws provide when there is no express definition of a given term in the specification, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art. See MPEP 2111.01. For example, Dictionary definitions can be used to provide broad and reasonable interpretation for the meaning of a given term in such cases. *“Dictionary definitions were used to determine the ordinary and customary meaning of the words “normal” and “predetermine” to those skilled in the art. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.”*; *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003)

For example, the dictionary defines the term “coupled” as “to connect”, “to join”, “to fasten together”, etc., (Definition of “coupled”; Merriam-Webster Online Dictionary;

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downloaded from <http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=coupled;>
downloaded 11/15/07).

As discussed above, the “108” element (the detector) is part of the device as a whole, as indicated by Figure 2 of the Kureshy reference. Thus, the detector is linked or joined with the “pipette receiving element” as parts of a single device.

Furthermore, the Sakka reference teaches the light source and the detector are “structurally coupled” coupled to the pipette tip receiving element. (e.g. Figure 1a; col.8, ll 46+).

Thus, the references’ teachings read on the instant claimed elements.

Applicants also requested clarification on how the references’ teachings read on the recitation of the instant claim 2. (Reply, pp.6-7, bridging).

Applicants are respectively directed to the above body of the rejection for detailed analysis of the references’ teachings.

Applicants also argue the Kureshy reference does not teach the elements recited in the instant claim 3. (Reply, p.7, para 2).

First, applicant’s argument is against the Kureshy reference alone. However, the above rejections are over the combination of Kureshy and Sakka references. In response to applicant’s arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Second, the recitation of “wherein the accurate aspirating is calculated from a reflected light signal that is detected by the first energy detector” is an intended use recitation of the claimed product or apparatus. Generally, intended uses or functional language do not afford patentable weight unless the intended use language can result in structural limitation to the product itself. In response to applicant's argument that the recitation of “the accurate aspiration is calculated from a reflected light...”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, both of the Kureshy and Sakka references teach the signals detected from the “detectors” are processed by a processor, and the position of the pipette tip element and/or the volume can be adjusted (see the above discussions). Thus, the devices taught by Kureshy and Sakka are capable of performing the intended uses recited in the instant claim 3 without evidence to the contrary.

Applicants argue the references do not teach “a data transfer interface” as recited in the instant claims 8 and 9. (Reply, p. 7, para 5 and 6).

Applicants are respectively directed to the above discussion under the body of the rejection over the cited references for detailed analysis of how the references’ teachings read on the instant claimed invention. For example, Kureshy et al, teach (see element 146, Fig 4; col.8, lines 20+) a data transfer interface, a microprocessor and/or a computer as a part of the device, which at least the “computer” reads on the data transfer interface of the instant claims, because a computer inherently has the property for remotely sending data.

Applicants further argue the references do not teach "biochip" as recited in the instant claim 10. (Reply, p.8, para 1).

The recited "biochip" is not a structural part of the claimed apparatus. It is a "material" that is worked on by the claimed apparatus. See MPEP 2115.

"Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963))." (emphasis added).

In this case, the "biochip" does not appear to be an integral part of the instant claimed apparatus and thus does not offer a structural limitation to the apparatus. The instant claim language only recites intended uses of the apparatus to operate on the "biochip". The recitation of "dispenses the fluid onto the surface of the biochip" of the instant claim 10 only recites intended use and/or functions that are capable of being performed by the instant claimed apparatus without evidence to the contrary.

Applicants also argue the Sakka reference does not "remedy certain defects" by asserting the Sakka reference does not teach "the first energy to be delivered to and received from the volume that is enclosed by the pipette tip..." (Reply, p.8, para 2).

First, applicants again have tried to traverse the above said art rejection by attacking each reference alone. In response to applicant's arguments against the references individually, one

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cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Second, the claim language is unclear as discussed in the subsequent section of the instant office action. It is not clear what specific structural limitation is offered by the said recitation of "...without passing across..."

In addition, the said recitation of "the first energy to be delivered to and received from the volume... without passing across a wall of the tip" is a recitation of intended use. In response to applicant's argument that "*the first energy to be delivered to and received from the volume... without passing across a wall of the tip*", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the Sakka reference teaches the light source coupled to the top of the pipette tip receiving element. (e.g. Figure 1a; col.8, ll 46+ of Sakka ref.), which indicates that the light source would exert inside the pipette tip. Applicants also pointed to Figure 3 of the Sakka reference to indicate that the reference does not teach the said recitation. However, Figure 3 of Sakka reference does not indicate that the light must pass through the wall for the detection. The Sakka reference teaches Figure 3 shows "the change of reflected light at the tip end face of the pipet tip" (e.g. col.4, lines 47+). Thus, the detected light is "reflected light, which does not necessarily traverse the "wall" of the pipette tip.

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Applicants also argue the Sakka reference does not teach "calculating". (Reply, p.8, para 3).

Again, applicants are arguing the intended uses and/or functional language of the instant claims. As pointed out by the applicants, the Sakka reference teaches "enables accurate quantitative sampling of a liquid..." (Reply, p.8, para 3, last line), which recitation clearly indicates that "calculation" is performed because "quantitative sampling" is required.

Applicants also argue there is no motivation to combine the Laugharns reference with the Kureshy and Sakka references. (Reply, pp.8-9).

Applicants are respectively directed to the above rejection for motivation statement to combine the references. Furthermore, applicants are also respectively directed to the recent Supreme Court decision, which forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396.*

In response to applicant's argument that the Laugharns reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Laugharns reference is relevant in the field of liquid sample handling and assay apparatus. The technologies for designing and making various samples (such as biological samples) handling apparatus are closely related. The Laugharns reference provides teachings of using a particular energy source

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(ultrasound transducer) for controlling samples, and the energy source/detector of the Kureshy and Sakka references are also for the purpose of controlling samples. Thus, it is no unreasonable for a person of ordinary skill in the art to combine the teaching of the references to arrive at the instant claimed invention.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-3, 5-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 5,141,871 in view of Sakka et al., US Patent No. 5,271,902 and Laugharn, Jr., et al., US Patent 6,948,843 (27 September 2005).

For claim 1, Kureshy et al., US Patent 5,141,871 claim analytical device with an automatic pipette, comprising: a pipette tip receiving element coupled to a mechanism that

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translates the pipette tip receiving element; wherein the pipette tip receiving element is further operationally coupled to a sensor that detects presence of a disposable polymer pipette tip that is removably coupled to the pipette tip receiving element; an energy source and an energy detector coupled to the pipette tip receiving element wherein the energy source provides energy to a surface of an assay element (e.g. a biochip) when the pipette tip approaches the surface of the assay element; and a processor electronically coupled to the energy detector, and wherein the processor controls movement of the pipette tip using a signal "from the second detector; and variations thereof.

US Patent 5,141,871 claims:

6. An analytical instrument in combination with a reservoir storing a fluid and employing a pipette for dispensing the fluid to an assay element, the instrument comprising: a pipette and a supply of disposable pipette tips to be affixed to a stem of the pipette; a conveyor for carrying an assay element; transport means for advancing the pipette to said supply of disposable pipette tips for replenishment of a tip, the transport means advancing the pipette between the reservoir and an assay element for dispensing the fluid; and wherein the analytical instrument further comprises an optical detection system which provides a light beam at a predetermined position relative to said conveyor for sensing the location of said pipette tip, the detection system providing a location signal indicating the presence of said tip at a reference location on a path of travel of the tip toward an assay element, the reference location being distant from the assay element; and said transport means moving said pipette to the reference location, said instrument including means responsive to the location signal for computing an additional distance of travel based on the height of an assay element above a reference surface of said conveyor and for advancing said pipette tip from said reference location by said additional distance for placing said tip in a position for dispensing the fluid to an assay element.

7. An analytical instrument according to claim 6 wherein said transport means in moving said pipette beyond said reference location to a second reference location on said travel path in the absence of an interruption of said light beam; and said means responsive to said location signal is further responsive to the location of said pipette on said travel path for signaling the absence of said tip on said stem upon the attainment

However, Kureshy et al., US Patent 5,141,871, do not explicitly claim a second energy source/detector.

However, Sakka, et al., remedies the deficiencies of Kureshy et al., as follows: For claim 1, Sakka et al, US Patent No. 5,271,902, in the same field of invention teach (see column 5, lines 8-22) teach a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and wherein first energy detector receives at least a portion of the first optical energy from the volume.

Sakka et al., (see column 7, lines 47-55) teach a processor electronically coupled to the first and second energy detectors, wherein the processor controls accurate aspiration of a predetermined volume using a signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.

For claim 6, Sakka et al., teach (see column 6, lines 38-41), the pipette tip has a volume of equal or less than 200 microliter (invention is effective in taking out quantitatively a sample in small amounts, particularly from 1 to 150 microliter).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the energy source and detection systems and a way of aspirating and dispensing an accurate volume of fluid taught by Sakka et al.

A person of ordinary skill in the art would have been motivated to combine the first energy source and the first energy detector coupled to the pipette tip receiving element creating a liquid level detecting device with Kureshy et al., because provides a way to gain a more accurate way of determining a volume to be aspirated or dispensed. Errors in quantifying the amount of such a small fluid volume (where the volume is equal

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to or less than 200 microliter) can result in drastic inconsistencies in assay results and experimental outcomes.

Finally, a person of ordinary skill in the art would have had a reasonable expectation of success because utilizing the system described by Sakka et al., because it has well known, robust elements for reliably detecting and quantifying a fluid volume and dispensing the fluid appropriately.

Discussion and Answer to Argument

11. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants traversed the above rejection with the same argument as the traversal over the art rejection. Thus, applicants are respectively directed to the discussion under the 35 USC 103(a) rejections for answer to arguments.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter Rejection

13. Claims 1-6 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by applicant's amendments to the claims.

Claim 1 has been amended to recite the followings:

- a.) "provides a first energy to a volume that is enclosed by the pipette tip without passing across a wall of the tip";
- b.) "...without the portion of the first energy passing across the wall of the tip";
- c.) "...and such that the second energy detector receives at least part of the second energy from the surface" (emphasis added)

as part of the claim amendment filed on 9/13/07. However, the instant specification does not provide support for the above said intended uses and/or functions of the claimed apparatus. Applicants also have not pointed to particular passages in the instant specification for support of the above said citations of the instant claims.

Claims 2-6 and 8-10 are dependent on claim 1 and encompasses all embodiments recited in the instant claim 1 and thus also encompasses the above said new matter.

If Applicant believes this rejection is in error, applicant must disclose where in the specification support for the entire scope of the amendment(s) and/or new claims can be found. As a result, Claims 1-6 and 8-10 represent new matter.

Second paragraph of 35 U.S.C. 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-6 and 8-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by applicant's amendments to the claims.

Claim 1 as amended recite "without passing across a wall of the tip" and "without the portion of the first energy passing across the wall of the tip", which recitations are unclear and render the claim indefinite. The instant claim 1 recites "provides a first energy to a volume that is enclosed by the pipette tip without passing across a wall of the tip" (emphasis added). That is the claim language is reciting that the "first energy" is provided to "a volume" that is "enclosed" by the "pipette tip", which seems to require the "first energy" to traverse the wall of the "tip" in order to deliver the "first energy" to the "enclosed" volume. However, the instant claim 1 subsequently recite "without passing across a wall of the tip", which appears to be in conflict with the proceeding recitation in the same claim.

Claims 2-6 and 8-10 are dependent on claim 1, and also do not clarify the said conflict in the instant claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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11/14/07

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